

Appl. No. : 09/720,041
Filed : April 2, 2001

Remarks

Applicants wish to thank the Examiner for the opportunity to discuss the status of this case in a telephone interview on January 14, 2003. As discussed, the Supplemental Amendment filed by Applicants on October 11, 2002 crossed in the mail with the Office Action issued on October 2, 2002. In view of the Office Communication and the discussion with the Examiner, Applicants believe that the time period for reply expired on January 23, 2003. Thus, the present paper is accompanied by a request for a one-month extension of time. However, if this understanding is incorrect, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Applicants believe that the amendments made in the Supplemental Amendment of October 11, 2002 have been entered. Thus, claims 32-62 are pending in the application. Claims 32, 36, 46, 49 and 59 are amended herein and claims 37-38, 51-58 and 60-61 are cancelled. New claims 63-68 are added. Support for the amendments to claim 32 is discussed below. Support for new claim 63 can be found in Table 2 of the original specification, as described in Example 14. Support for new claims 64-67 can be found in Example 15. Support for new claim 68 can be found in Example 1.

Objections to the Specification

The amendment filed under Article 34 in the PCT parent case was objected to by the Examiner under 35 U.S.C. §132 as introducing new matter into the disclosure. In particular, the Examiner found that the specification at the time of filing of the PCT parent case does not provide support for a minimum degree of hydrolysis or for the specific pH and temperature process conditions recited in the specification as amended.

The specification has been amended to remove the new matter. The replacement paragraph spanning pages 3 to 4 is consistent with claim 1. The description now states that the hydrolysis is to be terminated when the degree of hydrolysis is no greater than 10%. Support for this language can be found in the original text at lines 20-21 on page 4 and in tables 1 and 2 of the original text.

In addition, the replacement paragraph recites a temperature range of 20 to 65°C. This is the range of temperatures found at line 18 on page 5 of the original specification. Further, the pH

Appl. No. : 09/720,041
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ranges provided in the replacement paragraph find explicit support at lines 8 through 16 of page 5 of the original specification.

The replacement paragraph also recites that the hydrolysate has a solubility of at least 65% following inactivation of the enzyme. Support can be found in Example 5 of the specification as filed.

Support for testing of the bioactivity of the hydrolysate can be found in Example 1 and throughout the specification as originally filed.

In view of the amendments to the specification, Applicants request that the Examiner's objection be withdrawn.

Appl. No. : 09/720,041
Filed : April 2, 2001

Claim Rejections under 35 U.S.C. §112

Claims 32-58, 60 and 61 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. In particular, the Examiner found that the specification at the time of filing of the PCT parent case does not provide support for a minimum degree of hydrolysis or for the specific pH and temperature process conditions claimed.

Claim 32 has been amended herein and claims 37 and 38 have been deleted. As discussed above, support for the specific degree of hydrolysis, pH and temperature conditions and degree of solubility can be found in the specification as originally filed. For example, support for the termination of hydrolysis when the degree of hydrolysis is no greater than 10% can be found in the original text at lines 20-21 on page 4 and in tables 1 and 2 of the original text.

Support for the temperature range of 20°C to 65°C can be found, e.g., at line 18 on page 5 of the original specification. Further, the pH ranges find support at lines 8 through 16 of page 5 of the original specification.

Support for the hydrolysate having a solubility of at least 65% can be found, for example, in Example 5, while support for testing the hydrolysate for bioactivity can be found in Examples 1 through 5 and throughout the specification.

As the degree of hydrolysis, temperature and pH conditions and degree of solubility are supported by the original specification, Applicants request withdrawal of this rejection.

Claims 32-58, 60 and 61 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for the recitation of "to avoid substantial denaturation peptides" in claim 32. The claim has been amended such that it no longer recites this language.

In addition, the term "substantially white" in claim 55 was found to be indefinite. Without acquiescing in the Examiner's position, claim 55 has been cancelled.

Claim 46 was found to be indefinite because the term "said lactose content" lacks antecedent basis. Claim 46 has been amended to depend from claim 45, where there is antecedent basis for "said lactose content."

Claim 49 has been amended as suggested by the Examiner to correct a typographical error and insert a beta symbol prior to the term "-galactosidase."

Appl. No. : 09/720,041
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In view of the amendments described above, Applicants submit that the rejections under 35 U.S.C. §112, second paragraph should be withdrawn.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 32, 39, 45, 50 and 51 were rejected under 35 U.S.C. §102(b) as anticipated by Mellqvist et al. (U.S. Patent No. 4,847,096), which was found to disclose hydrolysis of a whey protein concentrate.

Claim 32 has been amended to include the step of testing the hydrolysate for bio-activity. Mellqvist et al. is concerned with fat removal from the whey protein concentrate and thus does not teach or suggest testing the hydrolysate for biological activity. As a result, claim 32 is not anticipated by Mellqvist et al. Claim 51 has been cancelled and claims 39, 45 and 50 depend from claim 32. Thus, Applicants request withdrawal of this rejection.

Claims 59 and 62 stand rejected under 35 U.S.C. §102(b) as anticipated by Komura et al. The Examiner asserts that Komura et al. discloses the peptide Leu-His-Leu-Pro-Leu-Pro and its use in treating hypertension.

This rejection is obviated by the present amendment to claim 59, which deletes reference to this peptide.

Claim 59 was rejected under 35 U.S.C. §102(b) as anticipated by Strachan (U.S. Patent No. 3,843,621), which was found to disclose the dipeptide valyl-phenylalanine.

Claim 59 was amended in the Supplemental Amendment filed October 12, 2002, to remove reference to the peptide VF. Thus, Applicants submit that this rejection is no longer applicable and should be withdrawn.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 32-40, 42-44 and 46-49 were rejected under 35 U.S.C. §103(a) as unpatentable over Mellqvist et al. (U.S. Patent No. 4,847,096).

As discussed above, claim 32 has been amended to include the step of testing the hydrolysate for bio-activity. Mellqvist et al. are concerned with fat removal and thus do not teach or suggest such a step.

Appl. No. : 09/720,041
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As the remaining claims depend from claim 32, Applicants request withdrawal of the rejection.

In addition, claims 32 and 41 were rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Mellqvist et al. and Shimamura et al. (EP 0 799 577). In particular, the Examiner found that one of ordinary skill in the art would have been motivated by the disclosure of Shimamura et al. to inactivate the protease in the process of Mellqvist et al. by ultrafiltration.

Again, as discussed above, Mellqvist et al. does not teach or suggest testing the hydrolysate for biological activity as claimed in claim 32. This deficiency is not made up for by the teachings of Shimamura. Thus, Applicants submit that claim 32 and claim 41, which depends from claim 32, are not obvious over the combination of Mellqvist and Shimamura.

Claims 32, 45 and 49 were rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Mellqvist et al. in view of Soehnlén (U.S. Patent No. 4,358,4464). Soehnlén does not teach or suggest testing a whey protein hydrolysate produced by the process of Mellqvist et al. for bio-activity, as claimed. Thus, Soehnlén does not make up for the deficiencies of Mellqvist et al. and applicants request withdrawal of this rejection.

Claims 32, 51 and 59-62 were rejected under 35 U.S.C. §103(a) as obvious over the combination of Mellqvist et al. and Mullally (Int. Dairy Journal 7:299-303 (1997)).

Claim 32 has been rejected as obvious over Mellqvist et al. alone. As discussed above, Mellqvist et al. does not teach or suggest testing the hydrolysate for bioactivity

Claims 51 and 60-61 have been cancelled, thus obviating their rejection. Claim 59 refers to particular peptides, none of which is disclosed in Mellqvist et al. or Mullally. Thus, Applicants submit that the rejection should be withdrawn.

Although the above arguments are believed to address the present rejections, Applicants would like to point out that Mullally teaches a process in which proteinases are inactivated following hydrolysis by heating at 80°C for 20 minutes (page 300, first column, second full paragraph). One of skill in the art would recognize that under such conditions the resulting hydrolysate would contain denatured proteins and thus would not be soluble. Further, Mullally describes an academic study of whether bioactive peptides could be recovered from whey protein

Appl. No. : 09/720,041
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digests. Thus, there is no teaching or suggestion in Mullally to modify the process to produce a hydrolysate with a high degree of solubility, as recited in claim 32.

Claim Rejections Under 35 U.S.C. §102/103

Claims 51-59 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Mellqvist et al.

Claims 51-58 have been cancelled herein. Claim 59 is directed to particular peptides, none of which is disclosed by Mellqvist et al. As a result, Applicants request withdrawal of this rejection.

Conclusion

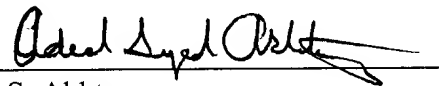
For the reasons presented above, Applicants respectfully submit that the present application is in condition for allowance and an early action to that effect is solicited. If any issues remain, the Examiner is invited to contact Applicants' counsel at the number provided below in order to resolve such issues promptly.

Respectfully submitted,

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Dated: February 21, 2003

By: _____



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